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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/800,351 | 03/12/2004 | Detlef Becker | P03,0116-01 | 9892 |

7590 11/28/2008
SCHIFF HARDIN LLP
Patent Department
6600 Sears Tower
233 South Wacker Drive
Chicago, IL 60606

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| EXAMINER |
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KAMAL, SHAHID

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| ART UNIT | PAPER NUMBER |
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3621

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11/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/800,351 | Applicant(s) BECKER ET AL. | |
| | Examiner SHAHID KAMAL | Art Unit 3621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/23/2008, 04/13/2007, 12/03/2004</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 17, 2008 has been entered.

Acknowledgements

2. Claims 36-37 are currently pending have been examined.
3. This Office Action is response to the application filed on September 23, 2008.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. The certify copy was filed on March 12, 2004.

Information Disclosure Statement

5. The Information Disclosure Statement filed on 23 September 2008, 13 April 2007 and 03 December 2004 has been considered. An initialed copy of the Form 1449 is enclosed herewith.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchosky (US Pub. No. 2003/0050803 A1) ("Marchosky") in view of Hotchkiss et al. (US Pub. No.: 2003/0140043 A1) ("Hotchkiss").

Referring to claim 36, Marchosky discloses the following:

a) providing a separate access right storage (storage 238) for association of said user identifiers (identifiers) with said access read right categories (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086);

b) determining an access right dependent on the data object (records 112) identifier (identifiers) and also on the user identifier (identifiers) by use of said user storage (storage 238) and said data object (records 112) category storage (storage 238), and when determining said access right, also determining an association of the user identifier (identifiers) with at least one of the access right categories so that the access right is also dependent on the association of the user identifier (identifiers) with the at least one access right category (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086); and

c) allowing the access by operating personnel (user) to the data object (records 112) dependent on the access right (see abstract, ¶¶ 0002, 0041, 0056, 0075).

Marchosky does not expressly disclose providing a separate user storage for association of user identifiers dependent on previously determined user ID information; providing a separate data object category storage for association of data object identifiers and access right categories, said data object identifiers forming structural connections to types of people or contextual associations with subject areas, and said data object identifiers also reflecting structural connections to studies or findings.

Hotchkiss discloses providing a separate user storage for association of user identifiers dependent on previously determined user ID information (see abstract, ¶¶ 0066, 0138-0149, 0169, 0209, 0219). providing a separate data object category storage for association of data object identifiers and access right categories, said data object identifiers forming structural connections to types of people or contextual associations with subject areas, and said data object identifiers also reflecting structural connections to studies or findings (see abstract, ¶¶ 0066, 0138-0149, 0169, 0209, 0219).

Therefore, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified of Marchosky for a record system with the features of Hotchkiss for a clinical research data management system and method in order to access this function, the user must login to the system and must have the appropriate role and associated rights to act as a registrar.

Referring to claim 37, Marchosky discloses the following:

a) providing a separate access right storage (storage 238) for association of said user identifiers (identifiers) with said access read right categories (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086);

b) determining an access right dependent on the data object (records 112) identifier (identifiers) and also on the user identifier (identifiers) by use of said user storage (storage 238) and said data object (records 112) category storage (storage 238), and when determining said access right, also determining an association of the user identifier (identifiers) with at least one of the access right categories so that the access right is also dependent on the association of the user identifier (identifiers) with the at least one access right category (see abstract, ¶¶ 0002, 0004, 0021-0022, 0086); and

c) allowing the access by operating personnel (user) to the data object (records 112) dependent on the access right (see abstract, ¶¶ 0002, 0041, 0056, 0075).

Marchosky does not expressly disclose providing a separate user storage for association of user identifiers dependent on previously determined user ID information; providing a separate data object category storage for association of data object identifiers and access right categories, said data object identifiers forming structural connections comprising at least one of work groups, research teams, personnel hierarchies, contents referring to people, or contextual associations with subject areas or studies in systems of the access rights, and said data object identifiers also reflecting at least one of affiliation with clinical studies, with series of diagnostic findings, or exposures over a long period of time, or with specific diagnostic image types.

Hotchkiss discloses providing a separate user storage for association of user identifiers dependent on previously determined user ID information (see abstract, ¶¶ 0066, 0138-0149,

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0169, 0209, 0219); providing a separate data object category storage for association of data object identifiers and access right categories, said data object identifiers forming structural connections comprising at least one of work groups, research teams, personnel hierarchies, contents referring to people, or contextual associations with subject areas or studies in systems of the access rights, and said data object identifiers also reflecting at least one of affiliation with clinical studies, with series of diagnostic findings, or exposures over a long period of time, or with specific diagnostic image types (see abstract, ¶¶ 0066, 0138-0149, 0169, 0209, 0219);

Therefore, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have modified of Marchosky for a record system with the features of Hotchkiss for a clinical research data management system and method in order to access this function, the user must login to the system and must have the appropriate role and associated rights to act as a registrar.

Examiner's Note:

8. The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

Response to Arguments

9. Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the patent examiner should be directed to Shahid Kamal whose telephone number is (571) 270-3272. The Patent examiner can normally be reached on Monday-Thursday (9:00am -7:00pm), Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Fischer can be reached on (571) 272-6779. The fax phone number for this origination where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-directed.uspto.gov>.

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Should you have any questions on accessing to the Private PAIR system, contact the Electronic Business Center (EBC) at 1(866) 217-9197 (toll free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 1(800) 786-9199 (IN USA OR CANADA) or 1(571) 272-1000.

Shahid Kamal
November 18, 2008

/Calvin L Hewitt II/

Supervisory Patent Examiner, Art Unit 3685